Setting up and initiating patient public involvement (PPI) as a collaborative process benefits research in its early stages

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Setting up and initiating PPI as a collaborative process benefits research in its early stages

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Objectives: *The value of involving patients and members of the general public in health research is recognised, but it is often done in a tokenistic manner, without real partnership between researchers and public and patient involvement (PPI) members, and at later stages of the research trajectory. This project applied recommendations from recent systematic reviews on PPI practices, to collaborate early in the research process.*

Methods: *Six PPI members volunteered to discuss the aims and methods of the study proposal. Three members had respiratory conditions, two had other health conditions, and one member was a carer. A lay summary of the study and patient-directed materials were supplied to PPI members preceding a face-to-face PPI meeting with the lead researcher and one co-investigator. Key recommendations were followed-up and decisions reported back to the PPI group.*

Results: *The meeting confirmed that the study was relevant and useful to service users and the public. The PPI group proposed changes for improved clarity and utility of some instruments, alongside strategies for participant recruitment and retention.*

Conclusion: *Early collaboration with the PPI group validated the research proposal, and helped improve the study design and methods. Collaboration will continue through data review to dissemination of results.*

Background

The value of involving service users (SUs) and members of the general public in research, including individuals living with particular health conditions, is increasingly recognised in health and social care research (e.g., Brett et al., 2012; Shippee et al., 2013). One of the United Kingdom's biggest health

research funders, the Department of Health-funded National Institute for Health Research (NIHR), was the first research organisation in the world to create an advisory group, INVOLVE, to ensure SUs and the public are equal stakeholders in health research, from priority setting and commissioning, through design and conduct, to dissemination of research (http://www.nihr.ac.uk/about/history-of-the-nihr.htm). Other major funders in health research now also require robust patient and public involvement (PPI) plans as fundamental elements of grant applications (O'Donnell & Entwistle, 2004). NIHR, in particular, supports early PPI by making funding available to NIHR grant applicants in the grant planning stage (Boote et al., 2015) to reimburse PPI members' time and travel costs to such initial meetings. The values of PPI are manifold, ranging from setting research agendas and funding priorities for research relevant to SUs and the public (e.g., Caron-Flinterman, Broerse, Teerling, & Bunders, 2005), providing a reality check for the research design (Staniszewska, Jones, Marshall, & Newburn, 2007), helping researchers with recruitment, and in the appropriate dissemination of results to the lay audience (Rhodes et al., 2002).

There are several approaches to PPI (Popay et al., 2013; Stewart & Liabo, 2012), such as contextual: focusing on where the PPI is undertaken (e.g., in funding decisions, a research environment, or within particular power structures); process-based: mapping PPI on the research continuum from priority-setting through commissioning to dissemination; or described by levels of engagement: consultative, collaborative, or user-led research (Shippee et al., 2013). Systematic reviews have highlighted a lack of harmonisation in these approaches and insufficient descriptions of the details of PPI in research reports, and identify the need for robust instruments for quantifiable evaluation of impact, alongside highlighting that PPI is biased towards qualitative as opposed to quantitative research (Boote, Wong, & Booth, 2015; Staley, 2009). PPI is still often used in a tokenistic way (Shippee et al., 2013); for example, it is often sought only after the study design has been finalised or after ethical approval obtained for the study, which results in a more complicated and time-consuming process for making changes to the study design, methods, or procedures following PPI

review. Recent systematic reviews on PPI in health and social care research (Brett et al., 2012; Shippee et al., 2013; Staley, Buckland, Hayes, & Tarpey, 2012) recommend approaching PPI as a process, calling for early PPI initiation (Boote, Baird, & Beecroft, 2010), and urge detailed description of PPI in research papers using standardised language. We invited PPI members early in our research project to collaborate on the design, conduct, and dissemination of a one-year quantitative postal questionnaire study in the NIHR Southampton Biomedical Research Centre (SBRC). The aim of the research project was to examine the emotional processing and illness representations of individuals living with asthma and their partners.

Our study is currently in the set-up stage; therefore, this paper describes the preparation and initiation stages of this collaborative PPI, mapped onto the synthesised framework proposed by Shippee et al. (2013). This framework consists of a PPI initiation component describing circular bi-directional relationships in the PPI process, and a linear component with distinct phases and roles of PPI through stages of a research project (see Figure 1, as adapted for this study). We also outline further PPI plans in our project, alongside considerations for future research.

Aims

Collaboration with the PPI group was conducted with the aim of ensuring that our research aims, objectives, and methods were appropriately articulated, and that the research was relevant and acceptable to the SUs and the public. We also wanted to ensure that the methods did not add unnecessary burden to participants, the data were meaningful, and that it would be possible to disseminate the findings from our study to participants and the public in a timely, accurate, comprehensible, and engaging manner.

Methods and results

The SBRC maintains a PPI database where SUs and members of the public interested in contributing to research in an advisory capacity can sign-up. There are several disease-specific groups, including one for respiratory disease. A dedicated PPI officer serves as the main contact between the public and the SCBR. The officer also offers training, mentoring, and support to PPI members until they feel confident enough to engage fully with the research teams. In PPI meetings, the officer acts as convener and facilitator, responsible for meeting co-ordination, set-up, and follow-up, and for ensuring PPI group members have equal chance to provide input.

The PPI group holds meetings every two months. JVS sent the study brief and documentation to the PPI officer who invited PPI members to review the materials at the next meeting and to gauge initial interest from the PPI group for the project. At this meeting, nine PPI members were present: three SUs with respiratory conditions, five members with other conditions, and one carer member. Based on this brief summary, the group declared interest in reviewing the study documentation in advance of a focused meeting that took place six weeks later. The PPI officer provided the researchers with feedback from the preliminary meeting that fed into the main PPI group meeting.

Six PPI members volunteered to prepare for, and attend, the main meeting. The lead researcher (JVS) provided a lay-language version of the study proposal that, together with the participant information sheet and psychometric instruments, were sent to the PPI members two weeks prior to the meeting. We prepared a list of questions for the group ahead of the main PPI meeting and ensured that we addressed the group's comments from the initial meeting. AC provided consultancy and supervision throughout the process, following her PPI work whereby patient representatives contributed to design, data collection, and analysis of a study exploring the role of patient participation groups in general practice (Pollard et al., 2014).

One, two-hour meeting was held in the SBRC offices and included the PPI group, the PPI officer, the lead researcher (JVS), who is a trainee health psychologist, and the co-investigator (PH), a professor of respiratory medicine who was also known to some members of the group as their consultant. We considered it important for both to be available to discuss the medical and the psychological aspects of the study. Three of the six attending PPI members were SUs with respiratory conditions, two members had other conditions, and one member was a carer. PPI group members were reimbursed for their time, in accordance with the INVOLVE PPI rates, and their travel expenses covered. In line with their policy, the PPI meeting was funded by the NIHR Research Design Services South-East in support of projects like ours that generate preliminary data with potential for a future NIHR grant application. The researchers briefly introduced the background, objectives, and design of the study. Since the PPI group included both carer and SU members, feedback from both perspectives was obtained, which was particularly important as our planned study included both SU and carer participants. The SU-directed materials (participant information, psychometric instruments, and measurement scales) were also discussed and the group suggested changes. Whilst it was explained to the PPI group that changes to validated instruments could not be made without losing fidelity, modifications were made to one scale that was not validated for clinical populations and that authors allowed to be modified for various user groups. This scale was also fundamental to the study design. The group also proposed changes to the participant information sheet for better readability and suggested that instead of implicit consent (i.e., whereby participants consent by returning questionnaires), they suggested that participants could be asked to sign a consent form to declare that they themselves had completed the questionnaires. Balancing this suggestion with the researchers' commitment to anonymity, we decided to insert a tick box instead of a signature line, confirming that the participant completed the questionnaire themselves.

The group suggested that, in addition to postal paper copies, the questionnaires could be made available to participants online. On further evaluation, this was deemed unfeasible as some

instruments had not been validated for electronic use. The PPI group also pro-actively suggested recruitment-boosting approaches; namely, working with Patient Ambassadors to raise awareness of this research study while SUs are waiting for their out-patient appointments, and posting a second batch of questionnaires should participants forget about the study over time.

The PPI meeting was followed up with an email update to PPI members who received a summary of decisions, actions, and outcomes from the meeting, including modified versions of the documents. Further PPI meetings will be scheduled, after recruitment reaches mid-way, to review data analysis plans. An additional PPI meeting will be organised to discuss recruitment boosting activities, should recruitment be sub-optimal. We plan to issue regular email updates to PPI members throughout the study. These activities will continue to be supported by the PPI officer.

Discussion

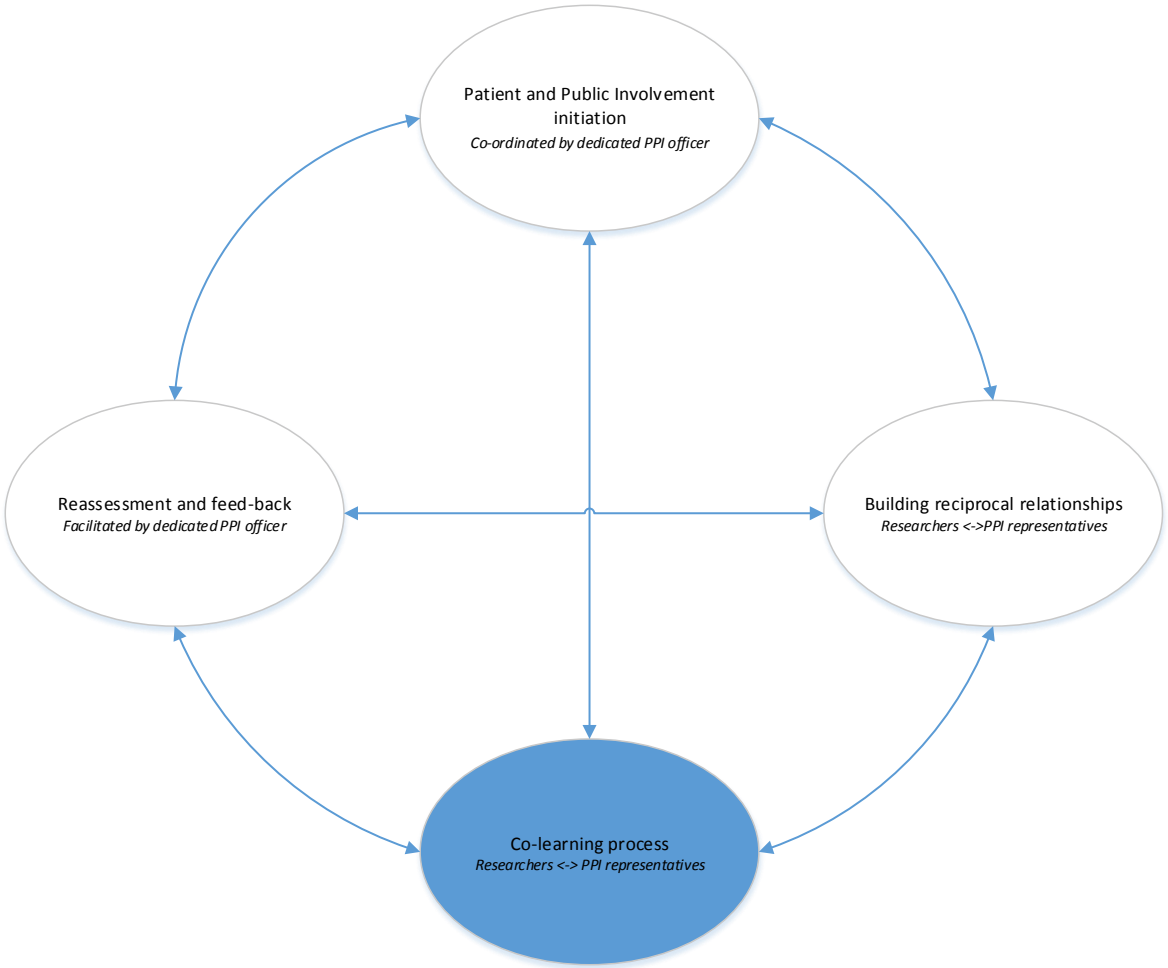
Addressing some of the shortcomings of PPI in health research revealed from recent systematic reviews, we initiated the PPI process at an early stage of our research project. This was mapped onto a modified framework by Shippee et al. (2013), with a detailed account of the PPI collaboration method. Although our study is in the early stages of data collection, consistent with previous PPI research, initiating early PPI collaborative processes has been valuable. The process validated the relevance of our research to SUs and the public (Ali & Crome, 2006); and contributed to a feasible study design through modifying our methodology to use meaningful psychometric instruments that promote participant engagement (Wyatt et al., 2008), whilst safeguarding research quality remained the researchers' responsibility (Stewart & Liabo, 2012). PPI collaboration also led to pro-active planning of actions to support participant recruitment and retention (Savage et al., 2006). Considering PPI within the synthesised framework helped us to view it as a process and maintain focus on actions ensuring reciprocity, continued engagement, defining boundaries of expertise, and

to identify critical stages in the lifetime of our research project requiring intensified PPI collaboration.

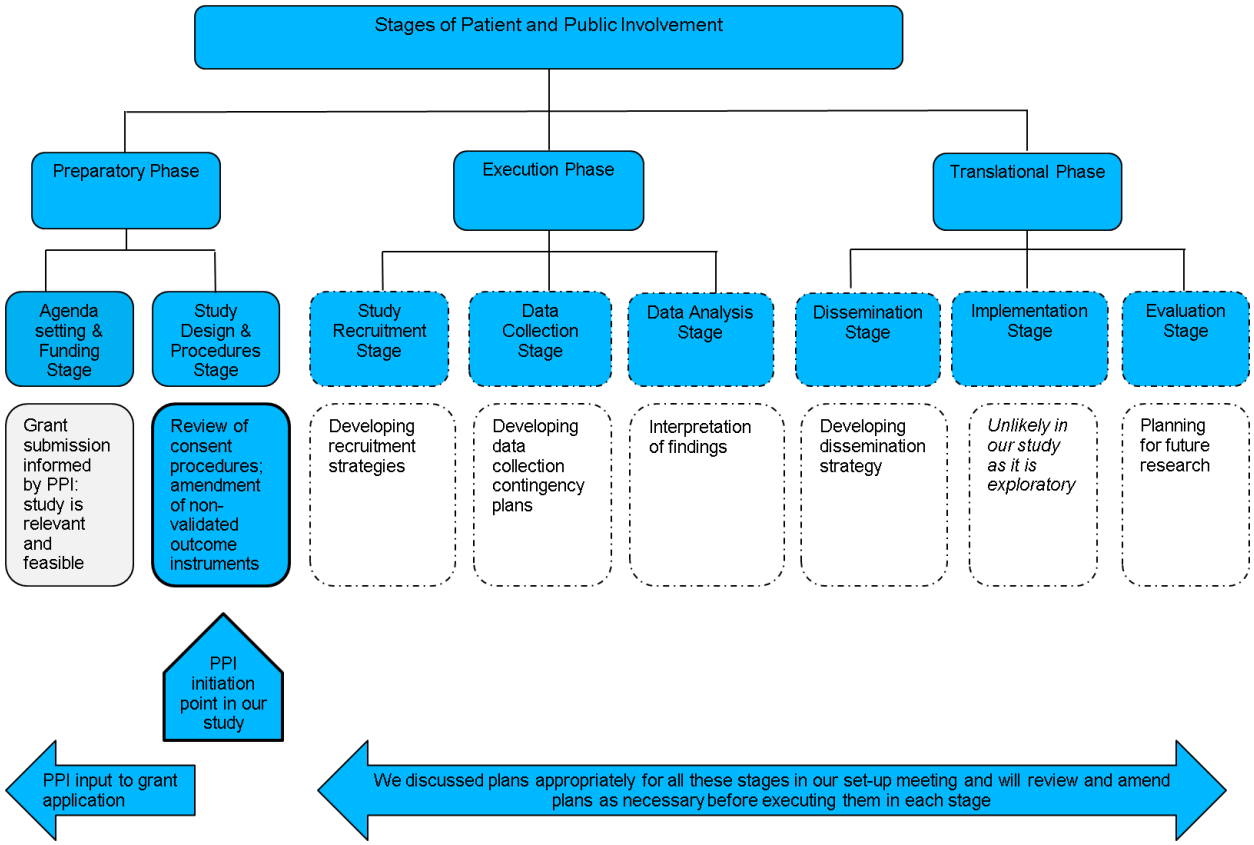
Having involved PPI in the planning stage of our project allowed swift adaptation of the protocol design and recruitment plans, without delays in setting up the study or having to amend the project in progress, with potential negative implications for timelines, budget, or data quality. Lastly, PPI collaboration strengthened a grant application submitted to the Asthma, Allergy and Inflammation Research Charity that awarded funding for this study, including two more PPI meetings.

Figure 1: PPI process of our study mapped to the framework modified from Shippee et al. (2013)

Framework part 1: Components of PPI initiation



Framework Part 2: PPI stages and phases



Future directions and recommendations

Initiating the process of collaborative PPI early in the research might validate the importance of the project, improve feasibility, design, participant recruitment, and retention, and increase the likelihood of funding. It is useful to consider PPI as a collaborative process where researchers and PPI members are equal partners with specific expertise.

Using this approach, we will use our funding for two more PPI meetings in our project – one during the data analysis stage to discuss initial findings, and one at the end of the study to plan dissemination. In the interim, we will keep our PPI members informed in writing. Additionally, we will closely monitor recruitment progress in our project and, should it fall behind, we will seek PPI members' input, even if this requires funding re-allocation. In keeping with our approach to date, we will document the process in detail, mapped to the framework we used, and hope that it will help

other researchers design, initiate, and maintain PPI collaboration. As researchers, we also advocate using a PPI framework, as it instils scientific rigour and ensures scrutiny in the process, and we call for the development of instruments in a collaborative PPI process for obtaining objective, quantitative data on PPI impact.

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References

Ali, K., Roffe, C., & Crome, P. (2006). What patients want consumer involvement in the design of a randomized controlled trial of routine oxygen supplementation after acute stroke. *Stroke*, *37*(3), 865-871. doi: http://dx.doi.org/10.1161/01.STR.0000204053.36966.80

Boote, J., Baird, W., & Beecroft, C. (2010). Public involvement at the design stage of primary health research: A narrative review of case examples. *Health Policy, 95*(1), 10-23. doi: http://dx.doi.org/10.1016/j.healthpol.2009.11.007

Boote, J. D., Twiddy, M., Baird, W., Birks, Y., Clarke, C., & Beever, D. (2015). Supporting public involvement in research design and grant development: A case study of a public involvement award scheme managed by a National Institute for Health Research (NIHR) Research Design Service (RDS). *Health Expectations, 18*(5), 1481-1493. doi: 10.1111/hex.12130

Boote, J., Wong, R., & Booth, A. (2015). 'Talking the talk or walking the walk?' A bibliometric review of the literature on public involvement in health research published between 1995 and 2009. *Health Expectations*, *18*(1), 44-57. doi: 10.1111/hex.12007

Brett, J., Staniszewska, S., Mockford, C., Herron-Marx, S., Hughes, J., Tysall, C., & Suleman, R. (2014). Mapping the impact of patient and public involvement on health and social care research: A systematic review. *Health Expectations*, *17*(5), 637-650. doi: 10.1111/j.1369-7625.2012.00795.x

Caron-Flinterman, J. F., Broerse, J. E., Teerling, J., & Bunders, J. F. (2005). Patients' priorities concerning health research: The case of asthma and COPD research in the Netherlands. *Health Expectations*, *8*(3), 253-263. doi: 10.1111/j.1369-7625.2005.00337.x

History of the NIHR. (Last edited 4 September 2015). Retrieved from http://www.nihr.ac.uk/about/history-of-the-nihr.htm on 21 September 2016

O'Donnell, M., & Entwistle, V. (2004). Consumer involvement in decisions about what health-related research is funded. *Health Policy*, *70*(3), 281-290. doi: http://dx.doi.org/10.1016/j.healthpol.2004.04.004

Pollard, L., Agarwal, S., Harrad, F., Lester, L., Cross, A., Wray, P. et al. (2014). The impact of patient participation direct enhanced services on patient reference groups in primary care: A qualitative study. *Quality in Primary Care. 22*(4), 189-199.

Popay, J., Collins, M., et al. (2013). PiiAF – The Public Involvement Impact Assessment Framework and Guidance website: http://piiaf.org.uk/. Accessed 21 September 2016.

Rhodes, P., Nocon, A., Booth, M., Chowdrey, M. Y., Fabian, A., Lambert, N., et al. (2002). A service users' research advisory group from the perspectives of both service users and researchers. *Health & Social Care in the Community*, *10*(5), 402-409. doi: 10.1046/j.1365-2524.2002.00376.x

Savage, C. L., Xu, Y., Lee, R., Rose, B. L., Kappesser, M., & Anthony, J. S. (2006). A case study in the use of community-based participatory research in public health nursing. *Public Health Nursing*, *23*(5), 472-478. doi: 10.1111/j.1525-1446.2006.00585.x

Shippee, N. D., Domecq Garces, J. P., Prutsky Lopez, G. J., Wang, Z., Elraiyah, T. A., Nabhan, M., et al. (2015). Patient and service user engagement in research: A systematic review and synthesized framework. *Health Expectations*, *18*(5), 1151-1166. doi: 10.1111/hex.12090

Staley K. (2009). Exploring impact: Public involvement in NHS, public health and social care research. INVOLVE, Eastleigh.

Staley, K., Buckland, S. A., Hayes, H., & Tarpey, M. (2014). 'The missing links': Understanding how context and mechanism influence the impact of public involvement in research. *Health Expectations*, *17*(6), 755-764. doi: 10.1111/hex.12017

Staniszewska, S., Brett, J., Mockford, C., & Barber R. (2011). The GRIPP checklist: Strengthening the quality of patient and public involvement reporting in research. *International Journal of*

Technology Assessment in Health Care 27(4). doi: http://dx.doi.org/10.1017/S0266462311000481

Staniszewska, S., Jones, N., Newburn, M., & Marshall, S. (2007). User involvement in the development of a research bid: Barriers, enablers and impacts. *Health Expectations*, *10*(2), 173-183. doi: 10.1111/j.1369-7625.2007.00436.x

Stewart, R., & Liabo, K. (2012). Involvement in research without compromising research quality. *Journal of Health Services Research & Policy*, *17*(4), 248-251. doi: 10.1258/jhsrp.2012.011086

Wyatt, K., Carter, M., Mahtani, V., Barnard, A., Hawton, A., & Britten, N. (2008). The impact of consumer involvement in research: An evaluation of consumer involvement in the London Primary Care Studies Programme. *Family Practice*, *25*(3), 154-161. doi: 10.1093/fampra/cmn019